# *LISTERIA MONOCYTOGENES* VERIFICATION AND SAMPLING RTE PRODUCT

FSIS Directive 10,240.4, Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program, provides instructions to CSIs for verifying whether establishments are complying with the regulations in 9 CFR 430, Requirements for Specific Classes of Product. In addition, this directive provides instructions for the FSIS verification testing program. Other important directives that provide sampling instructions are listed in the resources section at the end of this module.

## *Listeria monocytogenes* Verification

### Introduction

On June 6, 2003, FSIS published a regulation that requires establishments that produce certain RTE products to prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes*. The regulation, 9 CFR 430.4(a), states that *L. monocytogenes* is a hazard that an establishment producing a RTE product that is exposed to the post-lethality environment must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. It also states that RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes*. Establishments have three alternatives from which to choose in order to meet the requirements of this regulation. You are responsible for verifying that establishments are in compliance with the regulation.

### Definitions (§430.1)

***Antimicrobial agent.*** A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

***Antimicrobial process.*** An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

***Deli product.*** A ready-to-eat meat or poultry product that is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption.

***Hot dog product.*** A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

***Lethality treatment.*** A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

***Post-lethality exposed product.*** Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

***Post-lethality processing environment.*** The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

***Post-lethality treatment.*** A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

***Prerequisite program.*** A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called “prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

***Ready-to-eat (RTE) product.*** A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

**Additional Definition**

***Indicator organisms*** are bacteria used to determine objectionable microbial conditions of food, such as the presence of potential pathogens, as well as the sanitary conditions of food processing, production or storage areas. *Listeria spp*. are such indicators for *Listeria monocytogenes*.

## CSI Responsibilities for Verifying Compliance with 9 CFR Part 430.4

You must be familiar with the establishment products and processes that must comply with Part 430.4 in order to verify compliance. If necessary, you can ask establishment management whether they produce any RTE product that is exposed to the environment after the initial lethality step. The establishment is **not** required to comply with Part 430.4 if the RTE products produced are **not exposed** to the environment after the lethality step.

**Examples:**

- Hot dogs, exposed to the environment after peeling
  -Required to comply with Part 430, must choose one of the 3 alternatives
- Cooked ham, sliced and film wrapped in retail packages
  -Required to comply with Part 430, must choose one of the 3 alternatives
- Bologna, cooked in impermeable plastic casing which is not removed prior to packing
  -Not required to comply with Part 430

If the establishment is producing post-lethality exposed products, you should ask the establishment management which alternative they have chosen for each post-lethality exposed RTE product. You should inform them that, as set out in §430.4(c)(7), verification results that demonstrate the effectiveness of the measures they employ are to be made available upon request.

You should verify that the establishment is meeting the requirements of the alternative that it has chosen. Use the appropriate 01 or 03 procedure, for example, 03G01/02 for fully cooked, not-shelf-stable RTE products. If the establishment decides to produce different products using different alternatives, you should verify that they meet the requirements for **each** of the alternatives selected, for **each** of the post-lethality exposed RTE products.

**Note:** If an establishment is producing post-lethality exposed products and has failed to attempt to meet the requirements of **any** of the alternatives, you should contact the District Office for the issuance of an NOIE.

## Alternative 1

***9 CFR 430.4(b)(1)*** *Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes.*

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

**Gather information by asking questions**

When verifying compliance with the requirements in Alternative 1, seek answers to the following questions:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?

2. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?

3. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

4. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

5. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

**Assess the information**

To answer these questions you should:

- Review the HACCP plan,
- Review validation data (supporting documentation) for the post-lethality treatment,
- Review HACCP records,
- Review the Sanitation SOP and/or prerequisite programs associated with the use of the antimicrobial agent or process (as necessary), and
- Review Sanitation SOP and/or prerequisite program records (as necessary).

**Alternative 1 examples:**

**Example 1:** As part of the 03I01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 1. You review the plant's hazard analysis for sliced semi-dry sausage products such as Genoa salami, sandwich pepperoni, cervelat, thuringer, etc., and find that the fermentation, heating, drying, and packaging steps have been identified as CCPs in the hazard analysis and have been incorporated

into the HACCP plan. The hazard analysis identifies lowered acidity (pH) through the use of bacterial starter cultures and lowered water activity due to drying as measures to limit the growth of *L. monocytogenes (Lm)* in the finished product throughout the shelf life of the product. A steam pasteurization process after the product has been vacuum packaged has been identified as the treatment to reduce or eliminate post-lethality contamination by *Lm.* There are critical limits at the respective steps in the plan for pH, water activity, and time and temperature exposure for the steam pasteurization process. You decide to request the supporting documentation for the decisions made in the hazard analysis. The plant provides scientific literature and the results of challenge studies conducted by a processing authority that show that the pH and water activity (achieved in the product) inhibits the growth of *Lm* during its refrigerated shelf life and that the surface steam pasteurization treatment is effective in reducing or eliminating the level of pathogens resulting from the contamination from post-lethality exposure. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(1).

**Example 2:** As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 1. You review the plant's hazard analysis for cooked sausage products such as hot dogs, wieners, bologna, franks, etc., and find that the non-meat ingredient receiving, non-meat ingredient storage, cooking, and chilling steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. The hazard analysis identifies an antimicrobial coating (NOJAX® AL™) on the internal surfaces of cellulose casings that is transferred to the surface of the sausage product during thermal processing as a measure to reduce the level of *Lm* during the first days of storage (post-lethality impact) and inhibit the growth of *Lm* throughout the product's refrigerated shelf life. There are critical limits at the respective steps in the plan for supplier certification for the cellulose casings, casing shelf life, and casing storage temperature. The plant's hazard analysis identified growth of *Lm* as a potential hazard at the finished product storage step but determined that *Lm* growth was not a hazard reasonably likely to occur because it has control measures incorporated into a prerequisite program for the addition of sodium lactate and sodium diacetate (antimicrobial additives) in the formulation of the product. You decide to request the supporting documentation for the decisions made in the hazard analysis. The plant provides scientific literature in which NOJAX® AL™ coated casings applied to cooked hot dog type sausages effectively reduced *Lm* resulting from contamination from post-lethality exposure and suppressed the growth of *Lm* in the finished product throughout the shelf life of the product. It also provides several published research studies that show that sodium lactate and sodium diacetate inhibit the growth of *Lm* in commercial cured meat products throughout the shelf life of the product. The plant provides the procedures (verification activities) and the associated records it uses to ensure that sodium lactate and sodium diacetate are added at the concentration equivalent to those in the studies. The records for the past several months show that these ingredients have been added at the correct concentration. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(1).

**Determine compliance**

After you have gathered and assessed all available information pertaining to Alternative 1, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that

the establishment has not met all regulatory requirements, there is noncompliance. You should issue an NR under the appropriate 03 ISP code, and reference 9 CFR 430.4(b)(1) and the appropriate section of 417 (for HACCP and prerequisite programs) or 416.14 (for Sanitation SOP). You should verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative. You will receive more information about making compliance determinations in a later section.

**Noncompliance with Alternative 1**

The following are examples of noncompliance with Alternative 1.

1. The establishment has a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan, but does not have the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)1&2.)

2. The establishment has the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program, but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan. (Cite 430.4(b)(1) and 417.5(a)1&2.)

3. The establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism, but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan OR the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)1&2.)

4. The establishment has included a post-lethality treatment to reduce or eliminate *Lm* in its HACCP plan, but has not validated the effectiveness of the treatment. (Cite 430.4(b)(1) and 417.4.)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

## Alternative 2

***9 CFR 430.4(b)(2)*** *Use of either a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product OR an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes.*

Under Alternative 2, an establishment may select either Choice 1 or Choice 2 as follows.

**Choice 1** - An establishment that produces post-lethality exposed product that selects this alternative and chooses to use a post-lethality treatment (which may be an antimicrobial agent) that **reduces or eliminates** microorganisms on the product.

**OR**

**Choice 2** - An establishment that produces post-lethality exposed product and that selects this alternative and chooses to use an antimicrobial agent or process that **suppresses or limits growth** of *L. monocytogenes*.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

### Gather information by asking questions

When verifying compliance with the requirements in Alternative 2, seek answers to the following questions. Alternative 2 is based on the same requirements as Alternative 1, **except** that the establishment can choose to **just** have a post-lethality treatment that meets the requirements of questions 1-3 (Choice 1), **or** to just use an antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* throughout the shelf life of the product that meets the requirements of question 4 (Choice 2).

### Choice 1

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?

2. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?

3. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

### Choice 2

4. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

5. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

Also, if the establishment chooses Choice 2, you should seek answers to these additional questions, regarding the establishment's sanitation procedures.

Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:

1. provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?

2. identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism?

3. state the frequency with which testing will be done?

4. identify the size and location of the sites that will be sampled?

5. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

**Assess the information**

To answer these questions you should:

- Review the HACCP plan,
- Review validation data for the post-lethality treatment,
- Review HACCP records,
- Review the Sanitation SOP and/or prerequisite programs associated with the use of the antimicrobial agent or process (as necessary),
- Review the Sanitation SOP and/or prerequisite programs associated with the testing program for verification of effectiveness of sanitation procedures (as necessary), and
- Review Sanitation SOP and/or prerequisite program records (as necessary).

**Alternative 2 examples:**

**Example 1:** As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 2, Choice 1. You review the plant's hazard analysis for halved and sliced fully cooked deli-type products such as roast beef, turkey ham, ham, poultry rolls, etc., and find that the cooking, chilling and packaging steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. The hazard analysis identifies a hot water pasteurization step after the product has been vacuum packaged as the treatment to reduce or eliminate post-lethality contamination by *Lm.* The post-lethality pasteurization CCP has critical limits for the exposure time and the temperature of the hot water. You decide to request the supporting documentation for the critical limit for the post-lethality CCP. The plant provides published research studies as reference for the effectiveness of hot water pasteurization processes in reducing or eliminating *Lm*. Since the establishment is using

post-lethality pasteurization on different products and using different variables (exposure time and temperature) than that used in the studies, it provides the results of its own challenge studies to validate the use of the hot water pasteurization process to reduce or eliminate *Lm* for its specific products. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(2).

**Example 2:** As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 2, Choice 2. You review the plant's hazard analysis for fully cooked frozen breaded chicken products and find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. In addition to these CCPs, *Lm* was considered a potential hazard at the packaging step but was not likely to occur because the establishment has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You decide to request the supporting documentation for the decision made in the hazard analysis that *Lm* is not likely to occur in the post-lethality environment. The plant provides a scientific document that identifies the frozen temperature which would inhibit *Lm* growth in the finished product throughout the shelf life of the product. The plant also provides the procedures (verification activities) and the associated records it uses to demonstrate that products are frozen below the level which the scientific validation document establishes as preventing the growth of *Lm.* The records for the past several months show that the product is achieving the frozen temperature needed to suppress the growth of *Lm*. You review the establishment's SSOP and records and find that the plant is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The plant has identified the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *L. monocytogenes,* or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(2).

**Determine compliance**

After you have gathered and assessed all available information pertaining to Alternative 2, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You should issue an NR under the appropriate 03 ISP code, and reference 9 CFR 430.4(b)(2) and, depending where the use of the antimicrobial agent or process is addressed, either the appropriate section of 417 (for HACCP and prerequisite programs) or the appropriate section of 416 (Sanitation SOP). You should verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative. You will receive more information about making compliance determinations in a later section.

**Noncompliance with Alternative 2**

The following are examples of noncompliance with Alternative 2.

1. The establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan OR the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(2), 417.2, and 417.5(a)1&2.)

2. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only addresses the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(2), 416, and 417.5(a)1&2.)

3. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the conditions under which or at what point hold-and-test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism will be initiated. (Cite 430.4(b)(2), and 417.5(a)1&2.)

4. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the size of the site to be sampled. (Cite 430.4(b)(2), and 417.5(a)1&2.)

5. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not articulate its explanation as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained. (Cite 430.4(b)(2), and 417.5(a)1&2.)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

## Alternative 3

***9 CFR 430.4(b)(3)** Use of sanitation measures only*

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

**Gather information by asking questions**

When verifying compliance with the requirements in Alternative 3, seek answers to the following questions.

Does the establishment that produces post-lethality exposed product and that selects this alternative have on-going verification testing procedures that are designed to:

1. have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program?

2. test food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?

3. identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism?

4. state the frequency with which testing will be done?

5. identify the size and location of the sites that will be sampled?

6. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

**Also**, does an establishment producing a **deli product or a hot dog product**:

1. verify that its corrective actions are effective with respect to sanitation after an initial positive in the post-lethality processing environment are effective by follow-up testing that includes a targeted test of the specific site on the food contact surface area as necessary to ensure effectiveness of the corrective actions?

2. hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result, during this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes*, or an indicator organism?

3. sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*, in order to

be able to release into commerce the lots of product that may have been contaminated with *L. monocytogenes*?

4. document the results of the testing?

5. rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism?

**Assess the information**

To answer these questions you should:

- Review the HACCP plan, Sanitation SOP, and/or prerequisite programs associated with the testing program for verification of effectiveness of sanitation procedures.
- Review HACCP records, SSOP records, or the records associated with the prerequisite program

**Alternative 3 examples:**

**Example 1:** As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the plant's hazard analysis for fully cooked breakfast type products such as bacon, sausage patties, sausage links, etc., packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. *Lm* was considered a potential hazard at the packaging step but the establishment concluded that it was a hazard not likely to occur because it has *Listeria* control measures in a prerequisite program to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality environment. You review the establishment's prerequisite program and records and find that the plant is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. It also has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and testing frequency. The establishment provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *L. monocytogenes,* or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(3).

**Example 2:** As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the plant's hazard analysis for fully cooked deli and hot dog type products such as franks, sliced ham, sliced bologna, sliced roast beef, sliced turkey breast, etc., packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and are incorporated into the HACCP plan. *Lm* was considered a potential hazard at the packaging step but the establishment concluded that it was a hazard not likely to occur because it has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality

environment. You review the establishment's SSOP and records and find that the plant is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The plant has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food-contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained.

You find that the establishment verifies the effectiveness of the corrective actions it takes with respect to sanitation after an initial positive test on a food contact surface in the post-lethality processing environment through follow-up testing, including a targeted test of the specific site that is the most likely source of contamination by the organism, and other additional tests in the surrounding food contact surface area. When the establishment obtains a second positive test during this follow-up testing, it holds the lots of product that may have become contaminated by contact with the food contact surface until a test result indicates that the sanitation problem is corrected. The establishment only releases into commerce the lots of product that may have become contaminated with *Lm* from the food contact surface after it has sampled and tested the lots for *Lm* using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*. The establishment considers sampled product lots that test positive for *Lm* as adulterated and withholds them from entering commerce. The establishment destroys the held product, or reworks the held product using a process that is destructive of *Lm*. The establishment documents the test results and the disposition of the product. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(3).

**Determine compliance**

After you have gathered and assessed all available information pertaining to Alternative 3, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You should issue an NR under the appropriate 03 ISP code, and reference 9 CFR 430.4(b)(3) and, depending where the use of the sanitation measures are addressed, either the appropriate section of 417 (for HACCP and prerequisite programs) or the appropriate section of 416 (Sanitation SOP). You should verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan to determine whether the decisions made in the hazard analysis regarding the use of the prerequisite program remain valid, and the establishment's choice of another alternative. You will receive more information about making compliance determinations in a later section.

**Noncompliance with Alternative 3**

The following are examples of noncompliance with Alternative 3.

1. The establishment does not have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program. (Cite 430.4(b)(3), and 417.5(a)1&2.)

2. The written sanitation procedures the establishment is using to meet the requirements of this alternative only address the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)

3. An establishment that produces deli and hot dog products does not conduct follow-up testing of target sites on the food contact surface area that is the most likely source of contamination after an initial positive test for *Lm,* or its indicator organisms, to verify the effectiveness of its sanitation corrective actions. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)

4. An establishment that produces deli and hot dog products does not hold-and-test lots of product for *Lm,* or an indicator organism, that may have become contaminated by contact with the food contact surface when it obtains a second positive test for *Lm,* or an indicator organism, during its follow-up testing. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

## Labeling Claims

***9 CFR 430.4(e)*** *An establishment that controls L. monocytogenes by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.*

You should verify that the establishment has documented that the labeling claim is accurate, that the establishment has data to support the claim, and that the establishment has a sketch label approval from the Labeling and Consumer Protection Staff in Washington, D.C., on file.

If you have concerns about the validation data supporting the claim, you should contact the TSC or a CSO through supervisory channels for technical information. If the establishment does not have data to support the claim, the noncompliance would be documented on an NR using the appropriate HACCP procedure code and reference 430.4(e) and 417.5.

## Workshop, *Listeria monocytogenes* Verification

1) Establishments are required to comply with Part 430.4 (Control of *Listeria monocytogenes*) if they produce

a. Ready-to-eat products processed and sold in impermeable packaging.

b. Not ready-to-eat products with secondary inhibitors.

c. Ready-to eat products.

d. Ready-to-eat products exposed to the environment after the lethality step.

2) Fill in the blanks with one of the following:
Alternative 1
Alternative 2, Choice 1
Alternative 2, Choice 2
Alternative 3

a. _____Use of only a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product

b. _____Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes

c. _____Sanitation measures only, in the HACCP plan, SSOP, or prerequisite program, including testing of food contact surfaces to verify the effectiveness of the sanitation procedures

d. _____Use of an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes, along with a sanitation program addressing the testing of food contact surfaces to verify the effectiveness of the sanitation procedures

3. An establishment **MUST** implement hold and test procedures when a positive result for an indicator organism is found on a food-contact surface during follow-up testing (second consecutive food contact surface positive) if:

a. the establishment is producing RTE products exposed to the environment after the lethality treatment using either Alternative 1, 2, or 3.

b. the establishment is producing non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.

c. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.

d. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 2

4. An establishment **MUST** identify the conditions under which it will implement hold and test procedures after a positive result for an indicator organism is found on a food-contact surface if:

a. the establishment is producing either non-deli and hot dog type or deli or hot dog type RTE products exposed to the environment after the lethality treatment using either Alternative 2 (Choice 2) or Alternative 3.

b. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using either Alternatives 1, 2, or 3.

c. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 1 or Alternative 2, Choice 1.

d. the establishment is producing non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 1

**FSIS Compliance Guidelines ATTACHMENT 1 - CONTROL REQUIREMENTS for *LISTERIA MONOCYTOG***

| Requirements | → Increasing Risk Levels and Verification Tes | | | | |
|---|---|---|---|---|---|
| | **ALTERNATIVE 1** | **ALTERNATIVE 2** | | | |
| | Post-lethality Treatment AND Antimicrobial agent or Process | Post-lethality Treatment OR Antimicrobial agent or Process | | | |
| | | Post-lethality Treatment | Antimicrobial Agent or Process | | |
| **Validate effectiveness of post-lethality treatment** | X | X | | | |
| **Document effectiveness of antimicrobial agent or process** | X | | X | | |
| **Sanitation Program Requirements** | | | X | | |
| Testing food contact surfaces (FCS) | | | X | | |
| State testing frequency | | | X | | |
| Identify size and location of sites to be sampled | | | X | | |
| Explain why testing frequency is sufficient | | | X | | |
| Identify conditions for Hold-and-Test, when FCS (+) | | | X | | |
| **Additional Sanitation Program Requirements** | | | | | |
| Follow-up testing to verify corrective actions are effective after 1st FCS (+) | | | | | |
| If follow-up testing yields 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing. | | | | | |
| Hold and test product lots for *L. monocytogenes* using sampling plan that provides statistical confidence. Release, rework or condemn products based on results. Document results and product disposition. | | | | | |

OTHER REQUIREMENTS

- Post-lethality treatments must be included in the HACCP plan.
- Antimicrobial agents must be included either in the HACCP plan, Sanitation SOP, or prerequisite program.
- Sanitation programs must be included either in HACCP plan, Sanitation SOP, or prerequisite program. If in the Sanitation SOPs or prerequisite prog documentation for the hazard analysis determination that this hazard is not reasonably likely to occur.
- Verification testing for sanitation in the post-lethality environment may be for *Listeria monocytogenes, Listeria* spp. *or Listeria*-like organisms.
- Product testing must be confirmed for *Listeria monocytogenes*.
- Establishment must maintain sanitation in the post-lethality environment per 9 CFR 416.
- If *L. monocytogenes* controls are in HACCP plan, establishment must validate and verify effectiveness per 9 CFR 417.4
- If *L. monocytogenes* controls are in Sanitation SOPs, their effectiveness must be evaluated per 9 CFR 416.14.
- If *L. monocytogenes* controls are in prerequisite programs, the program and results must be included in documentation required by 9 CFR 417.5
- Establishment must make verification results available to inspection program personnel.

## FSIS Compliance Guidelines ATTACHMENT 2 - CHART OF RTE VS NRTE PRODUCTS

| TYPE | CLASS | PROCESSING CATEGORY ISP CODE | REG REQUIRED SAFETY LABELING | WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS |
|---|---|---|---|---|
| A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product). | Not-ready-to-eat | • Raw Product Ground – ISP 03B<br>• Raw Product Not Ground – ISP 03C<br>• Not Heat Treated Shelf Stable – ISP 03E<br>• Heat Treated –shelf stable – ISP 03F<br>• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H<br>• Products with secondary inhibitors Not Shelf Stable – ISP 03I<br>• | Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required. | • Use of SHI labeling (Some establis SHI labeling application).<br>If it is not obvious that the product is raw<br>• Features on labeling are conspicuo aware that product must be cooked conveyed through the product nam may also be conveyed by the use o name that is associated with a stat panel, or by a burst stating such th cooked," "see cooking instructions<br>• Validation that:<br>a. Cooking and preparation instructio to destroy pathogens.<br>b. Instructions are realistic for the inte |
| A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user.<br>This includes meals, dinners, and frozen entrees. | Not-ready-to-eat | • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H | Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended. | • Validation that:<br>a. The meat/poultry component receiv treatment for pathogens.<br>b. Cooking and preparation instructio to destroy pathogens.<br>c. Instructions are realistic for the inte<br>• Features on labeling are conspicuo aware that product must be cooked conveyed through the product nam may also be conveyed by the use o name that is associated with a stat panel, or by a burst stating such th cooked," "see cooking instructions<br>• If necessary, hazard analysis shou on the label are needed related to contact of contents) and prevention promptly refrigerate leftovers).<br>NOTE: Inspection program personnel a the establishment does not follow the gu |
| A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does not need to receive a lethality treatment by the intended user. | Ready-to-eat | • Not Heat Treated Shelf Stable – ISP 03E<br>• Heat Treated Shelf Stable – ISP 03F<br>• Fully Cooked Not Shelf Stable – ISP 03G<br>• Products with secondary inhibitors Not Shelf Stable – ISP 03I | If the product is not shelf stable labeling such as keep refrigerated or frozen is required. | • See part 417 of the meat and poult |

# Sampling RTE Product

FSIS is continuously updating its sampling programs in order to keep pace with changes in policy. FSIS directives and notices for current sampling programs contain specific instructions for you to follow. It is important to read **recent** issuances, so that when you are requested to collect a sample you have the latest information.

**Note:** The instructions in this material will apply until FSIS has Alternative and production volume information available to develop the new risk-based RTE sampling program. At that time, FSIS Directive 10,240.4 will be revised.

## Introduction

FSIS's microbiological testing program is designed to verify that the establishment's food safety system is effective. FSIS sampling is done to verify that FSIS performance standards and regulations are met. FSIS tests RTE products for pathogens because of the public health impact (there could be a breakdown in the lethality step, or post lethality contamination may occur). The pathogens of public health concern are *Listeria monocytogenes*, *Salmonella*, and, for certain products, *E. coli* O157:H7.

During the1980's, *Listeria monocytogenes*, which previously was known as a contaminant of dairy products, began to emerge as a problem in processed meat and poultry products. In 1998, an outbreak occurred which resulted in 101 illnesses, 15 adult deaths, and 6 stillbirths. *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes*, or other pathogens, or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes*.

## Definitions

***Aseptic*** means "free from pathogenic organisms." An aseptic technique implies that you do not add any organisms (pathogenic or not) to the sample when it is collected. It does not imply that the sample is aseptic. The purpose of aseptically collecting a sample is to prevent contaminating the sample or the surrounding product/product contact area. That is why it is important to aseptically collect a sample even when the sample is intact. Wash and sanitize your hands before collecting an intact sample, but it is not necessary for you to sanitize the area and put on gloves. Good personal hygiene is essential anytime a sample is collected, whether it is intact or not.

***Environmental samples*** are samples from surfaces that have

- indirect or potential contact with exposed RTE product in the RTE production area (mop handles, outer garments, etc., that may be handled by a person who may touch RTE product), or

- non-contact surfaces in a RTE production area (e.g., floors, drains, walls, overhead structures).

***Food contact surface*** is specific to the RTE verification testing program. A food contact surface is the equipment or utensil surface with which exposed RTE product has direct contact (for example, conveyor belt, tabletop, knife blade). A food contact surface does not include items that may have indirect or potential contact with exposed RTE product.

***Food contact surface samples*** are a collection of samples (e.g., swabs) from food contact surfaces that represent the conditions under which the sampled lot was processed. The samples are collected during the production shift, not pre-operational, but without disrupting production, such as during breaks and at the end of a shift.

***Intact*** means product in the final packaged form (immediate container) in which it will be shipped. The lab receives the sample in the same immediate container that the consumer will, so whatever is in the product the lab gets is what is in the consumer's product, too.

***Recall*** is a plant's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). Product that is adulterated and has left the establishment's control may be subject to a recall. The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the Recall Management Division (RMD) of all factors in the situation. FSIS Directive 8080.1 gives additional details on recalls.

***RTE production area*** is one where exposed RTE products are stored, further processed, or packaged. This is the area from which food contact surface samples and environmental samples are taken and analyzed for *L. monocytogenes* or indicator organisms.

***Sample*** is a collection of product that represents a larger group (the sampled lot) that has passed the plant's pre-shipment HACCP review.

***Sampled lot*** is the amount of product represented by the sample. For microbial issues, the actual (affected) product represented by the sample is usually interpreted as the product produced from clean-up to clean-up. Often, factors like the plant's coding system, the pathogen of concern, the processing and packaging, the equipment, the plant's sampling programs, the HACCP plan monitoring and verification activities, the SSOP records, etc., are considered when determining how much product is actually represented by the sample.

***Short-weight or slack-filled*** containers meet the definition of an intact sample, but with less product (e.g., a liner from a bulk package which contains approximately 2-lb of product, folded down and sealed in the same manner that the bulk product is normally packed to prevent product contamination). A short-weight or slack-filled sample is one that has progressed through all the production steps that the product normally goes through (not changed in any way that would affect the processing parameters). A short-

weight or slack-filled sample may appear to the lab as a non-intact sample and may be discarded if you do not indicate that it is short-weight or slack-filled in block 28.

***Subsequent production*** is all product produced after the sampled lot. It is not usually part of the sampled lot, but it may or may not be affected product.

## PBIS Procedure Code 05B02

Procedure 05B02 is used for the collection of samples for microbial analyses with a direct bearing on food safety and public health. (05B02 is also used for import samples.) Since a directed sample request is not a scheduled procedure, 05B02 is recorded as unscheduled, "performed," on the Procedure Schedule on the day that you collect the sample.

## Sample Initiation

There are several ways that sampling is initiated. Most commonly, you will receive a directed sample request from OPHS (Office of Public Health and Science). When OPHS schedules a sample to be taken at an establishment, they will send a Requested Sample Programs Form, 10,210-3. Once the form is received, you are to **always** collect a RTE product sample. FSIS Directive 10,210.1, Unified Sampling Form, lists the products and pathogens and toxins for which FSIS may collect and test samples. For example, FSIS may analyze a ready-to-eat meat and poultry product for *Salmonella* and *Listeria monocytogenes*. Plus, if the product is dry or semi-dry fermented sausage or fully-cooked meat patties, then it will also be analyzed for *E. coli* O157:H7.

Inspector-generated samples are initiated by FSIS in-plant personnel, based on a suspicion about the product or process. You and your front line supervisor will determine when inspector-generated sampling should occur. Before a sample is taken, you must obtain an FSIS Form 10,210-3 from OPHS. The front line supervisor, District Office, or Washington headquarters may also initiate directed samples.

Special project samples are taken when FSIS is alerted to a foodborne illness outbreak by a state or local government, or when there is a special project such as baseline studies.

## Steps in Sampling

There are 5 general steps in actually sampling product.

1. Determine which product to sample
2. Notify plant management
3. Collect the sample
4. Pack and mail the sample and form
5. React to the results

### Step 1: Determine Which Product to Sample

If a specific product is not pre-selected for sampling in block 18 of the sample request form, you should sample products based on the following priority.

a. Post-lethality exposed RTE products under **Alternative 3**, sampled in this order.
   1. Deli meats
   2. Hot dogs
   3. Deli salads, pate, meat spreads
   4. Other product

b. If no post-lethality exposed RTE products are produced using Alternative 3 criteria, then sample post-lethality exposed RTE products using **Alternative 2** criteria in the following order.
   1. Sample product produced using only a growth inhibitor.
   2. Sample product produced using post-lethality treatment.

c. If no post-lethality exposed RTE products are produced using Alternative 3 or 2 criteria, then sample post-lethality exposed RTE products using **Alternative 1** criteria.

d. If no post-lethality exposed RTE products are produced, then sample any RTE product that likely will be used as a deli-type item, such as a cook-in-bag roast beef.

e. If none of the above is available, select any other RTE product.

### Step 2: Notify Plant Management

Plant management must be notified whenever a sample is going to be taken. This gives management the option of holding the product represented by the sample pending test results. You should notify management enough in advance to allow them to hold the product, but not soon enough to allow them to alter the process. You should discuss the notification timeframe with plant management prior to any sample requests being received in order to have an agreed upon protocol in place.

In the case of RTE products, you must give plant management a handout stating that you will take a sample and that the establishment may wish to voluntarily hold the product pending microbial analyses results. (See Attachment 1)

You should verify that all product represented by the sample (that is, the sampled lot) is held by the establishment, should it elect to do so.

**Step 3: Collect the Sample**

If possible, only collect the sample and mail the samples from the establishment's current day's production that has passed the pre-shipment record review. If not possible, such as in establishments where production is held off-site before completion of the pre-shipment record review, or the pre-shipment record review is performed at a later date, but there are no additional lethality or other pathogen control steps, collect samples of the current day's production, refrigerate or freeze them, keep them in a secure location, and postpone mailing the samples until the pre-shipment record review is complete, and the product is eligible for shipment. After the establishment completes the pre-shipment record review, you should prepare the samples to be sent to the laboratory on the next available Federal Express pickup day.

If, for whatever reason, the plant decides not to ship the sampled product, but to rework it or dispose of it, then you must discard the sample by returning it to the plant. Send the form back to the lab, in block 33 mark "other" and explain.

In most cases, block 4 has a pre-printed date that tells you when to collect a sample. It will say "within 30 days of", that means within 30 days **after** the date printed, you should have collected a sample.

If the plant does not produce the requested product in the 30-day time frame, then you will check code 72 in block 33 of the requested sample form and return the form to the lab.

**The sample must be in an intact consumer-ready package.** Place the sample into the plastic bag provided by OPHS. Identify the sample and place it in a secure location. The sample should be kept refrigerated until shipped.

Some products may be produced with components other than meat or poultry, such as RTE frozen dinners. If the product has the meat portion in a separate compartment (frozen dinners, snacks, etc.), then you must ensure that enough meat is available for the requested sample size. Several packages may need to be sent so that the laboratory has enough product to run the analyses.

Sometimes intact products may be very large. If a short-weight or slack-filled sample is not an option, contact the lab via Outlook and request a shipper large enough to contain the size sample you need to collect.

When a RTE sample does not appear intact because of the way the company packages product you should provide additional information, for example, "this is an intact sample," in block 28.

**Step 4: Pack and Mail the Sample and Form**

**Complete the form.** Complete all requested information on the form. The FSIS laboratories will discard any samples with incomplete forms. The following is a list of important blocks of the sample request form.

Block 9: Name & receiving laboratory – Filled in by laboratory; you should check the shipping container to see if the right address is on the shipping container.

Block 14: Project number

Block 18: Additional instructions – Read carefully to find out what sample needs to be taken for RTE sampling.

Block 19: Date collected – Enter the date you collected the sample. Check block 4 to make sure this date is after the date printed in block 4, but no more than 29 days after that date.

Block 20: Date sent to lab – Enter the date you mailed the sample.

Block 22: Product held – Check the "yes" box if the sampled/affected product was held, or check the "no" box if the establishment did not hold the product.

Block 28: Remarks – You must fill in requested information, such as,

- product name, production code, date or lot code.
- the time of sample collection (hour and minute).
- if the intact sample is short-weighted/slacked-filled.
- if the sample is dry or semi-dry fermented sausage.
- the name of the establishment contact person and phone number.
- a note that "This is an intact sample" if the sample does not appear intact.

Block 29: Collector's signature – Sign your name.

Block 30: Name of collector – Print your name.

Block 31: Badge number – Put your badge number here. This identification is necessary for a traceable chain of custody if the Agency has to take the establishment to court based on the FSIS laboratory results.

Block 32: Telephone number at the establishment – Provide the telephone number where you can be reached at the establishment.

**Identify sample and paperwork, and place them into the bag provided by the lab.** Double check the sample paperwork and the FedEx air-bill to make sure that the sample is sent to the lab indicated on the sample form. Follow the directions for sealing samples in FSIS Directive 7355.1, Rev. 2. Place one of the small bar code stickers from the 5 part sample seal set (7355-2A/B) on the bagged sample, and another on the sample form. Put the sample form in a bag to protect it. Put the sample and the form into a zip-lock bag, and attach the Identification Label, 7355-2B, by folding it down over the opening of the bag.

**Pack the sample.** Samples should be shipped in FSIS-furnished containers, unless special arrangements are made with the lab. Pack one sample per shipping container to avoid confusion. (If absolutely necessary, multiple samples can be sent in one container, as long as they each are accompanied by the appropriate completed form.)

The shipping containers you use should have been sealed by the lab with red and black striped tamper-evident tape across the top and bottom.

When multiple product packages are used for a single sample, all of them must be mailed in the same shipper.

Pack the sample in this order.

1. Freeze pack
2. Coolboard
3. Zip-lock bag containing the identified sample and paperwork
4. Extra small bar code sticker that was not used
5. Foam plug
6. Close shipper with Container Seal (7355-2A)

A frozen freeze pack must be added for product that was stored refrigerated or frozen. Shelf stable products should also contain the freeze pack to ensure that the product does not get over-heated during shipping. The “coolboard” goes on top of the freeze pack to separate the freeze pack from the sample. The bagged sample is then put into the shipper. Do not use filler material in the shipping container. Any unused bar code sticker needs to go into the shipper with the sample. This insures that it won’t accidentally get used on another sample, and allows the lab to account for all 5 parts of the seal/label. Alternatively, the unused bar code may be retained with the file record of sample collection. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper.

Some types of RTE containers are not very durable, for example, plastic tubs and aluminum trays. If these containers are bounced around inside a shipper, they may crack or burst. In these cases, it is acceptable to put some packing material around the sides of the sample container to prevent the sample container from bouncing around inside the shipper.

An FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal.

**Mail the sample.** Microbiology samples are mailed so they arrive at the lab the next day. You can mail samples on Friday because the contract carrier will deliver on Saturdays. (However, they do not pick-up on Saturday.) A “Saturday Delivery” label must be used. Put a checkmark in the “Saturday Delivery” portion of the delivery air-bill or stamp. Samples should not be held over the weekend if it is avoidable. However, if a sample must be held over the weekend it should be refrigerated or frozen, depending on the directive instructions.

**FSIS Laboratories** There are three FSIS Field Service Laboratories. The Eastern lab is in Athens, GA, the Midwest lab is in St. Louis, MO, and the Western lab is in Alameda, CA.

The FSIS labs are responsible for providing the sampling supplies. Whenever supplies are needed, e-mail a request through Outlook following FSIS Notice 54-02.

**Step 5: React to Results**

**Access LEARN to track sample receipt and results.** LEARN means Laboratory Electronic Application for Results Notification (see FSIS Directive 10,200.1). LEARN is a computer application that notifies FSIS personnel and establishment management of the receipt and status of samples sent to the FSIS analytical laboratories for testing. LEARN reports when a sample was received at the lab, if it was discarded and the reason for the discard, and the results of the analysis when it is completed.

When a sample is submitted for analysis, you must check LEARN the following day to see that the sample was received and was not discarded. After logging onto LEARN, you can view a 28-day history of sampling for an individual establishment by going to the following address.

http://dchqintra/learn/estindex1.cfm

When you go to the LEARN address, you have three options.

1. Enter the form number,
2. Enter a single establishment number to obtain all the results in the database for that establishment, or
3. Go to a customizable list of samples for all establishments in a circuit.

Option 3 is particularly useful if you have a patrol assignment, since you can see the status of the samples of all the establishments you are responsible for at one time, on one screen, without having to type in several different individual establishment numbers as in Option 1. You can narrow the information to show just a particular type of sample.

Click on “Submit” to see the collection date, the form number, and whether the sample was “Received” or “Not Analyzed”.

Once the analyses are complete, the results are posted in the results column. Microbial analyses results are reported as positive or negative and some are also listed as presumptive positive. OPHS e-mails sample results to plants that complete FSIS Form 10,230-2, FSIS Establishment E-mail (Internet) Address Collection Form, and submit it to OPHS. **You should provide sample result information to establishment management even if the establishment receives e-mail notifications from OPHS.**

Turnaround Time for Positive and Negative Results

| Analysis | Minimum Number of Days from Receipt When the Result Is | |
|---|---|---|
| | Negative | Positive |
| *Salmonella* | 1 | 5 |
| *Listeria monocytogenes* | 3 | 6 |
| *E. coli* O157:H7 | 1 | 4 |

## Pathogen in a Product Sample

If any RTE product sample collected by FSIS or by the establishment (after pre-shipment review) tests positive for a pathogen of public health concern, product in the sampled lot is adulterated. You are to issue an NR using the appropriate 03 ISP code. FSIS will request a recall if any product in the sampled lot has been shipped.

**Note:** If the positive result is from an establishment test and the establishment held the affected product, you should not issue an NR unless the establishment fails to implement corrective actions or to safely dispose of the sampled product lot.

You should verify that establishment implements corrective actions in accordance with the appropriate regulation. A positive sample result for a pathogen of public health concern is a food safety hazard, and this is true regardless of what type of program the establishment is using to address the pathogen. In all cases, the plant must meet the corrective action requirements in the HACCP regulations, 9 CFR 417.3. The establishment must meet 9 CFR 417.3(a) when the pathogen is addressed in the HACCP plan, and 9 CFR 417.3(b) if the positive sample result is considered an unforeseen hazard, or a deviation not covered by a specific corrective action. If the pathogen is controlled through the Sanitation SOPs, then the establishment must also address the corrective action requirements for SSOP, 9 CFR 416.15. If the pathogen is controlled through a prerequisite program that is used to support the decision that a hazard is not likely to occur at a particular point in a process, then the establishment must perform a reassessment, according to 9 CFR 417.4(a)(3), which states that when there is a change in the process that could impact the hazard analysis, a reassessment must be performed. In each situation, you will need to review all information available to determine whether the establishment has implemented all appropriate corrective actions.

You should verify the establishment disposition of the sampled product lot by verifying that the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products. If the establishment elects to destroy the product, you should verify that it has destroyed the sampled lot. If the establishment elects to rework the product, you should verify that it has reworked the sampled lot with a process that is destructive of *L. monocytogenes*. Verify that the hazard analysis has considered the use of the reworked product.

The DO may coordinate scheduling intensified verification sampling through OPHS to verify the establishment's corrective and preventive measures. This sampling should not be initiated until the corrective and preventive measures have been put in place.

Product that tests positive may be shipped to another federally inspected facility for further processing. It must be transported under FSIS Form 7350-1, Request and Notice of Shipment of MPI Sealed Meat/Poultry.

## Pathogen on a Food Contact Surface Sample

If a post-lethality exposed RTE food contact surface sample collected by FSIS or by the establishment (after pre-shipment review) tests positive for a pathogen of public health concern, product passing over the surface is adulterated. You are to issue an NR using the appropriate 03 ISP code. FSIS will request a recall if any product in the sampled lot has been shipped.

**Note:** If the positive result is from an establishment test and the establishment held the affected product, you should not issue an NR unless the establishment fails to implement corrective actions or to safely dispose of the sampled product lot.

You should verify that establishment implements corrective actions in accordance with the appropriate regulation. A positive sample result for a pathogen of public health concern is a food safety hazard, and this is true regardless of what type of program the establishment is using to address the pathogen. In all cases, the plant must meet the corrective action requirements in the HACCP regulations, 9 CFR 417.3. The establishment must meet 9 CFR 417.3(a) when the pathogen is addressed in the HACCP plan, and 9 CFR 417.3(b) if the positive sample result is considered an unforeseen hazard, or a deviation not covered by a specific corrective action. If the pathogen is controlled through the Sanitation SOPs, then the establishment must also address the corrective action requirements for SSOP, 9 CFR 416.15. If the pathogen is controlled through a prerequisite program that is used to support the decision that a hazard is not likely to occur at a particular point in a process, then the establishment must perform a reassessment, according to 9 CFR 417.4(a)(3), which states that when there is a change in the process that could impact the hazard analysis, a reassessment must be performed. In each situation, you will need to review all information available to determine whether the establishment has implemented all appropriate corrective actions.

You should verify the establishment disposition of the affected product, by verifying that the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products. If the establishment elects to destroy the product, you should verify that it has destroyed the affected product. If the establishment elects to rework the product, you should verify that it has reworked the sampled lot with a process that is destructive of *L. monocytogenes*. Verify that the hazard analysis has considered the use of the reworked product.

The DO may coordinate scheduling intensified verification sampling through OPHS to verify the establishment's corrective and preventive measures. This sampling should not be initiated until the corrective and preventive measures have been put in place.

**Positive Environmental Samples**

An establishment may or may not conduct environmental sampling, other than on food contact surfaces, under its HACCP plan, Sanitation SOP, or a prerequisite program. If the establishment is conducting such sampling, and positive results are received, you are to verify that the establishment takes the appropriate action as outlined in the program under which the sampling is conducted. If the establishment is conducting such sampling, but is not addressing the sampling under HACCP, Sanitation SOP, or a prerequisite program and you find that such sampling is resulting in persistent positive results, you are to notify the DO. Also, FSIS personnel, other than CSIs, may conduct environmental sampling when necessary and as directed by the DO.

## Workshop, Sampling RTE Product

1) _____ is a verification activity for RTE products.

a. Enforcement
b. Sampling
c. Recall
d. Documentation

2) You are assigned to a plant which produces a variety of ready-to-eat (RTE) products. You receive a directed sample request from OPHS for a RTE product. Which of the following would you choose, based on the priority listed in Directive 10,240.4?

a. Post-lethality exposed RTE product, produced under Alternative 1
b. Post-lethality exposed RTE product, produced under Alternative 2
c. Post-lethality exposed RTE product, produced under Alternative 3
d. RTE Product not exposed to the environment after the initial lethality step

3) If possible, only collect and mail RTE samples from the current day's production that has passed

a. the Critical Control Point for lethality.
b. the establishment's pre-shipment record review.
c. all monitoring and verification procedures.

4) Fill in the blank. When you get a directed sample request for RTE product, you should _____ collect a sample.

5) FSIS sampling is done to

a. verify that FSIS performance standards and regulations are met.
b. validate HACCP plans and compare results to plant analyses.
c. generate public support.
d. monitor in-plant activities.

6) PBIS procedure code 05B02 will never appear as a scheduled procedure on your procedure schedule.

a. True
b. False

7) RTE sliced ham is analyzed for (circle all that apply)

a. *E. coli* O157:H7.
b. *Salmonella*.
c. *L. monocytogenes*.
d. *Staphylococcus enterotoxin*.

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8. When a plant has a sanitation program that includes sampling RTE product as part of the HACCP plan, you do not have to collect RTE samples.

a. True
b. False

9. When a plant has a sanitation program that includes sampling RTE product as part of the HACCP plan, and they receive a positive for *L. monocytogenes*, what actions would we expect them to do? (circle all that apply)

a. Hold the affected product
b. Implement corrective actions per §417.3(a)
c. Make appropriate disposition of the sampled product
d. Notify the IIC

10. When a plant has a sanitation program that includes sampling RTE product contact surfaces as part of the SSOP program, and they receive a positive for *L. monocytogenes*, what actions would we expect them to do? (circle all that apply)

a. Hold the affected product
b. Implement corrective actions per §417.3 & 416.15
c. Make appropriate disposition of the sampled product
d. Notify the IIC

11. Under what circumstance might the DO (through OPHS) schedule intensified verification sampling? What would be the purpose?

12. When should a RTE sample be sent to the lab for a *L. monocytogenes* directed sample?

a. the day before the “use by” date
b. just prior to packaging
c. the first day FedEx is available after the pre-shipment review is completed
d. as soon as the lot is assembled

13. Plant management must be notified of pending sample collection

a. when you receive the analysis result (either from LEARN or the DO).
b. after pre-shipment review has been completed.
c. enough in advance to allow the plant to hold the product, but not soon enough to allow it to alter the process.
d. because of the Freedom of Information Act (FOIA).

14. How many samples should be submitted per shipping container?

a. 1
b. 2
c. 3
d. 4

15. If a sample is too large for the shipping container, you

a. have the plant use a different package to enclose the product.
b. contact the FSIS lab for a larger shipping container.
c. select a different product produced under the same HACCP plan.
d. contact the ADME.

16. An establishment produces fully cooked ham, in the not shelf stable (03G) processing category. This product is produced using Alternative 2, Choice 1. The establishment performs a post-lethality treatment on the hams immediately following packaging. As a verification activity for the post-lethality treatment, it samples the hams for *Lm*, and holds product pending results. This morning, the establishment received a positive result for *Lm* from one of its samples. Based on the information presented so far, answer the following questions.

    a. Which corrective action regulation would apply in this situation?

    b. What would you verify in this case? List all that apply.

    c. Would you issue an NR?

    d. Would FSIS request a recall?

    Continuing with the above situation, while you are reviewing the establishment's corrective action documentation, you observe "The product represented by the sample will be relabeled as not fully cooked. The future production of these products will be as heat-treated, not fully cooked. The HACCP plan will be reassessed and modified to change the cooking temperature. The label will be changed to include cooking instructions."

    e. What would you do next?

**ATTACHMENT 1**

**Notice to Give Plant Management When a Sample is Taken**

To Establishment Manager:

X The inspector will be taking a sample of your Ready-to-Eat meat and/or poultry product or raw ground beef product to be tested for microbial hazards. Sampling is one component of verifying your HACCP system.

X To protect public health and to avoid the negative impact of a recall, FSIS strongly recommends that you hold all product represented by the sample until results are obtained.

X Most negative results are available within 3 days; confirmed positive results may take up to 8 days. Results will be provided to you be the inspector or the District Office. For results of future samples, you can receive results by e-mail (contact your District Office for a copy of FSIS Form 10,230-2).

X If a recall is needed, FSIS expects you to initiate the recall in a timely fashion—usually the same day. See FSIS Directive 8080.1 for further details.

X It is your responsibility to determine the amount of product represented by the sample. As a guide, FSIS considers all product produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up, including start to finish under extended clean-ups) to be an appropriate definition of a sampled lot. See FSIS Directives 10,240.2 Rev. 1 and 10,010.1.

X If a test result is positive, and you have distributed the product, FSIS will request that you conduct a recall. FSIS may determine that more product or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

**ATTACHMENT 2**

## Resources

Currently, there are several directives associated with microbial sampling of RTE products that fall into the 03E, 03F, 03G, and 03I process categories. This list is current as of 10/03. Each CSI should review the pertinent directives prior to obtaining a sample. The review should consist of checking to see if the directive is the current version. The FSIS website lists those directives that have been published most recently. The Outlook Folder (Public Folders ➜ All Public Folders ➜ Agency Issuances ➜ Directives or Indexes and Checklists) has a listing of the current directives (and any revisions, etc.). The actual directives are posted under the Directives Folder. New listings may also be posted in LEARN on the "What's New" page.

| **Selected FSIS Sampling References for RTE (03E, 03F, 03G, and 03I)** | | |
|---|---|---|
| **FSIS Directive Number** | **Directive Title** | **Directive Date** |
| 5000.1, Rev 1 | Verifying an Establishment's Food Safety System | 5/21/03 |
| 7355.1, Rev 2 | Use of Sample Seals for Laboratory Samples and Other Applications | 12/3/02 |
| 8080.1, Rev 3 | Recall of Meat and Poultry Products | 1/19/00 |
| 10,200.1 | Accessing Laboratory Sample Information via LEARN | 7/19/01 |
| 10,210.1, Amend 5 | Unified Sampling Form | 2/11/03 |
| 10,230.2, Amend 1 | Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses | 9/4/92 |
| 10,240.4 | Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program | 10/2/03 |
| 10,600.1 | Sample Shipment Procedures | 10/6/83 |

**ATTACHMENT 3**

## Discard Reasons

This table includes common discard reasons for samples. The codes are not given in this table since they are used for tracking purposes. You should review the sample and paperwork before submitting them to the lab to ensure these mistakes are not made.

| **COLLECTED SAMPLES/NOT ANALYZED** |
|---|
| RTE-Sample Submitted in Error |
| No Sample Received with Form |
| Collected Outside Scheduled Time Frame |
| Temperature Too High |
| Tissue/Sample Spoiled/Rancid |
| Container Damaged |
| Commingled Tissues |
| No Identification on Tissues |
| Wrong Tissue/Sample for Requested Analysis |
| Insufficient Tissue or Sample |
| Delayed Shipment |
| Shipped on Friday w/o Saturday Delivery label |
| Sample Forwarded to Another Lab |
| Original Form Not Submitted w/Sample |
| Target Tissue Not Received |
| No Form Received with Sample |
| Original Form Altered by Sample Submitter |
| Plant Has It's Own Testing Program-Sample Submitted |
| Laboratory Problem* |
| No Freeze Packs/Coolants in Sample Box |
| Sample Container Leaking |
| Collection Date Not Day Prior to Sample Receipt |
| Cooked Product |
| Excessive Fat |
| Sent to Wrong Lab |
| Sample ID # on Bag does not match ID # on Form |
| Non-Intact Sample Package |
| Raw Product Submitted for RTE program |
| Security Seal Missing or Not Intact |
| Temperature Too Low |
| No Accredited Lab Tests Performed |
| Headquarters/ TSC/DO Discard |
| Sampling Instructions Not Followed |

## ATTACHMENT 4

| *Internal lab code here* | U.S. DEPARTMENT OF AGRICULTURE<br>FOOD SAFETY AND INSPECTION SERVICE<br>**REQUESTED SAMPLE PROGRAMS**<br>☐ FOOD CEMISTRY ☐ MICROBIOLOGY ☐ RESIDUE | *Barcode here*<br>1. SAMPLE FORM NO. |
|---|---|---|

**PART 1. SAMPLE COLLECTION AND MAILING INSTRUCTIONS**

| 2. SAMPLE TYPE CODE | 3. EST. NO. | 4. COLLECT TISSUES/SAMPLES ON | | | 5. REGION/ DISTRICT | 6 STATE | 7. CIRCUIT/IFO |
|---|---|---|---|---|---|---|---|
| | | Day of: | Week of: | Wthin 30 days of: | | | |

| *8. ESTABLISHMENT ADDRESS/SAMPLE COLLECTION ADDRESS (i.e., Est.,Retail Store)* | 9. NAME & ADDRESS OF RECEIVING LABOATORY |
|---|---|
| | |

| 10. SLAUGHTER CLASS CODE | 11. SPECIES TO COLLECT | 12. TISSUE | 13. ANALYSIS REQUESTED |
|---|---|---|---|
| | | | |

| 14. PROJECT NO. | 15. COUNTRY OF ORIGIN | 16. COUNTRY COPY | 17. FOREIGN EST. NO. |
|---|---|---|---|
| | | | |

18. ADDITIONAL INSTRUCTIONS

***PART II. COLLECT SAMPLE INFORMATION (To be compluted by sample collector)***

| 19. DATE COLLECTED | 20. DATE SENT TO LAB | 21. PRODUCT TEMPERATURE | 22. PRODUCT HELD ☐ YES ☐ NO |
|---|---|---|---|
| 23. FSIS N9540-1 NO. | 24. LOT NO. | 25. IMPORTS ☐ NORMAL (06) ☐ INCREASED (07) ☐ SPECIAL (53) ☐ HOLD (24) | |

| 26. PRODUCER/DEALER/OWNER-NAME/ADDRESS/STATE/ZIP CODE | *27. ANIMAL ID (Tag No.)* |
|---|---|
| | |

28. REMARKS

| 29. COLLECTOR'S SIGNATURE | *30. NAME OF COLLECTOR (Print)* | 31. BADGE NO. | 32. TELEPHONE NO. AT EST. |
|---|---|---|---|
| | | | |

**33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE**

(72) ☐ *REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date)*

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIED/CLASS OR PRODUCE THE REQUESTED PRODUCTS *(If checked, plant will be removed from this sampling program)*

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ *OTHER (Explain)*

**PART III, LABORATORY RECEIPT INFORMATION**

| 34. SAMPLE PACKAGING<br>☐ 3034 Intact Package ☐ 3035 Non-intact Package | 35. SAMPLE RECEIPT DATE |
|---|---|
| | |

| 36. PRODUCT CODE | 37. NO. SAMPLES IN COMPOSITE | 38. SAMPLE RECEIPT TEMPERTURE |
|---|---|---|
| | | |

| 39. SAMPLE RECEIPT CONDITION CODE | 40. SEAL CONDITION CODE | 41. DISCARD CONDITION CODE |
|---|---|---|
| | | |

**FSIS FORM 10,210-3(3/97)**

## Regulations

**9 CFR 430.1, Definitions.**

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called “prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

**9 CFR 430.4, Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products.**

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes*.

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) Alternative 1. Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(2) Alternative 2. Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) Alternative 3. Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes*, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of L. monocytogenes or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with Sec. 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with Sec. 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.